UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

# NOTICE OF ALLOWANCE AND FEE(S) DUE

23850

7590

01/05/2009

KRATZ, QUINTOS & HANSON, LLP 1420 K Street, N.W. Suite 400 WASHINGTON, DC 20005 EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 01/05/2009

	APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
•	10/580,415	04/03/2007	Norimasa Miura	060387	6081

TITLE OF INVENTION: CANCER DIAGNOSTIC METHOD

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$755	\$300	\$0	\$1055	04/06/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

#### HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

#### PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE

Mail Stop ISSUE FEE Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or <u>Fax</u> (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

maintenance fee notificat	ions.				, and/or (b) indicating a sep		
CURRENT CORRESPONDE	ENCE ADDRESS (Note: Use Bl	ock 1 for any change of address)	F	ee(s) Transmittal. Th	is certificate cannot be used	or domestic mailings of the for any other accompanying ent or formal drawing, must	
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KRATZ, QUINTOS & HANSON, LLP 1420 K Street, N.W. Suite 400				Certificate of Mailing or Transmission  I hereby certify that this Fee(s) Transmittal is being deposited with the U States Postal Service with sufficient postage for first class mail in an env addressed to the Mail Stop ISSUE FEE address above, or being face transmitted to the USPTO (571) 273-2885, on the date indicated below.			
WASHINGTON	, DC 20005		[			(Depositor's name)	
			Ī			(Signature)	
						(Date)	
APPLICATION NO.	FILING DATE		FIRST NAMED INVENT	OR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/580,415	04/03/2007		Norimasa Miura		060387	6081	
TITLE OF INVENTION:							
APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DU	E PREV. PAID ISSU	E FEE TOTAL FEE(S) DUE	E DATE DUE	
nonprovisional	YES	\$755 •	\$300	\$0	\$1055	04/06/2009	
EXAMI		ART UNIT	CLASS-SUBCLASS				
CHUNDURU, SU		1637	435-006000				
1. Change of corresponde CFR 1.363).	nce address or indicatio	n of "Fee Address" (3/		e patent front page, li to 3 registered pater			
Change of correspo	ondence address (or Cha /122) attached.	inge of Correspondence	or agents OR, altern	atively,			
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.			registered attorney of 2 registered patent a	name of a single firm (having as a member a red attorney or agent) and the names of up to tered patent attorneys or agents. If no name is no name will be printed.			
3. ASSIGNEE NAME AT	ND RESIDENCE DATA	A TO BE PRINTED ON	THE PATENT (print or	type)			
PLEASE NOTE: Unle	ess an assignee is ident	ified below, no assignee	data will appear on the	patent. If an assign	ee is identified below, the o	document has been filed for	
(A) NAME OF ASSIC		sicuon of this form is two	(B) RESIDENCE: (CI				
Please check the appropri	ate assignee category or	categories (will not be p	rinted on the patent):	☐ Individual ☐ C	orporation or other private gr	oup entity  Government	
4a. The following fee(s) a	re submitted:	4	b. Payment of Fee(s): (I	lease first reapply a	ny previously paid issue fee	shown above)	
Issue Fee			A check is enclosed.				
	o small entity discount p	permitted)	☐ Payment by credit card. Form PTO-2038 is attached. ☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any				
Advance Order - #	of Copies		overpayment, to De	posit Account Numb	er (enclose a	an extra copy of this form).	
5. Change in Entity Stat	,	· ·					
* *	SMALL ENTITY state				LL ENTITY status. See 37 C		
NOTE: The Issue Fee and interest as shown by the r	l Publication Fee (if requeeords of the United Sta	uired) will not be accepte tes Patent and Trademark	ed from anyone other tha k Office.	n the applicant; a reg	istered attorney or agent; or t	he assignee or other party in	
Authorized Signature				Date			
Typed or printed name				Registration No.			
This collection of informa an application. Confident submitting the completed this form and/or suggestic Box 1450, Alexandria, Vi Alexandria Vireinia 223	ation is required by 37 C iality is governed by 35 application form to the ons for reducing this builtinginia 22313-1450. DC 13-1450.	CFR 1.311. The informati U.S.C. 122 and 37 CFR USPTO. Time will vary rden, should be sent to the ONOT SEND FEES OR	ion is required to obtain 1.1.4. This collection is y depending upon the in the Chief Information Of COMPLETED FORMS	or retain a benefit by the estimated to take 12 dividual case. Any collicer, U.S. Patent and TO THIS ADDRESS	he public which is to file (an minutes to complete, includi omments on the amount of ti Trademark Office, U.S. Dep S. SEND TO: Commissioner	d by the USPTO to process) ng gathering, preparing, and ime you require to complete partment of Commerce, P.O. for Patents, P.O. Box 1450,	

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UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

DATE MAILED: 01/05/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,415 04/03/2007		Norimasa Miura	060387 6081	
23850 75	90 01/05/2009	EXAMINER		
KRATZ, QUINT	OS & HANSON, LI	CHUNDURU, SURYAPRABHA		
1420 K Street, N.W	<i>V</i> .	ART UNIT	PAPER NUMBER	
Suite 400 WASHINGTON, I	OC 20005	1637		

## Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

	Application No.	Applicant(s)				
Notice of Allowability	10/580,415	MIURA ET AL.				
Notice of Allowability	Examiner	Art Unit				
	Su <b>ry</b> aprabha Chunduru	1637				
The MAILING DATE of this communication appe All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RI of the Office or upon petition by the applicant. See 37 CFR 1.313	(OR REMAINS) CLOSED in this app or other appropriate communication IGHTS. This application is subject to	olication. If not include will be mailed in due	ed course. <b>THIS</b>			
1. $\square$ This communication is responsive to <u>12/1/08</u> .						
2. ☑ The allowed claim(s) is/are <u>1</u> .						
<ul> <li>3.  Acknowledgment is made of a claim for foreign priority ur</li> <li>a)  All b)  Some* c)  None of the:</li> <li>1.  Certified copies of the priority documents have</li> </ul>						
2. Certified copies of the priority documents have	been received in Application No	·				
<ol><li>Copies of the certified copies of the priority do</li></ol>	cuments have been received in this i	natio <b>n</b> al stage applica	tion from the			
International Bureau (PCT Rule 17.2(a)).						
* Certified copies not received:						
Applicant has THREE MONTHS FROM THE "MAILING DATE" noted below. Failure to timely comply will result in ABANDONM THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.		complying with the red	quirements			
<ol> <li>A SUBSTITUTE OATH OR DECLARATION must be subm INFORMAL PATENT APPLICATION (PTO-152) which give</li> </ol>			IOTICE OF			
5. CORRECTED DRAWINGS ( as "replacement sheets") mus	et be submitted.					
(a) $\square$ including changes required by the Notice of Draftspers	(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached					
1)  hereto or 2)  to Paper No./Mail Date						
(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date						
Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).						
6. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.						
Attach we suit (a)						
Attachment(s) 1. ☐ Notice of References Cited (PTO-892)	5. ☐ Notice of Informal P	atent Application				
2. Notice of Draftperson's Patent Drawing Review (PTO-948)	6.  Interview Summary					
3. ☐ Information Disclosure Statements (PTO/SB/08),	Paper No./Mail Dat 7.					
Paper No./Mail Date 4. ☐ Examiner's Comment Regarding Requirement for Deposit	8. 🛛 Examiner's Stateme	ent of Reasons for Allc	wance			
of Biological Material	9.					

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## **DETAILED ACTION**

1. The response to the office action filed on December 01, 2008 has been considered and

acknowledged.

2. The following is an examiner's statement of reasons for allowance:

Claim 1 is allowed.

The present invention is drawn to a cancer diagnostic method comprising selectively extracting RNA from a cell fraction of a bodily fluid, reverse transcribing RNA to generate cDNA and PCR amplification of cDNA in the presence of a fluorescence dye, using primer pair SEQ ID NO. 1 and 2 and quantitating the amplification product. The closest prior art (US 6,475, 789) teach said RT-PCR, however, the prior art does not teach the said specific primer pair and presence of a fluorescence dye during PCR as reflected by the instant amended claims. Thus the instant invention was not taught or obvious over the closest prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Art Unit: 1637

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Suryaprabha Chunduru/

Primary Examiner, Art Unit 1637